

REMARKS

Reconsideration of the present application as amended is requested. Applicant notes that the arguments regarding method claims 205-216 have been rejected. Consequently, these claims have been withdrawn, although Applicants reserve the right to re-introduce these claims if the apparatus claims are deemed allowable. The obviousness-type double patenting rejection was repeated but Applicants' indication regarding a Terminal Disclaimer was acknowledged. The indefiniteness rejection in the First Office Action was addressed by the amendments in Applicants' prior response.

The pending claims 117, 118, 121, 125-129 and 204 were again rejected as anticipated by U.S. Patent No. 5,192,327 to Brantigan. Claim 117 was also rejected as anticipated by the patent of Samani (No. 5,645,599), along with dependent claims 201-203.

Turning first to the rejection based on the Samani '599 Patent, Applicants have amended the lone independent claim 117 to define each of the plurality of elements as being "substantially similarly configured". This amendment is supported by the specification as well as by some of the dependent claims that describe one embodiment of the elements as being a wafer. In contrast, the implant in Samani includes a U-shaped bracket and a bearing cushion that is placed between arms of the bracket. It is apparent that the bracket and the cushion are not "substantially similarly configured", nor could they be for the implant to work as contemplated in Samani. It is believed that claim 117 as amended avoids anticipation by the Samani '599 Patent. It is therefore requested that the rejection of claim 117, as well as its dependent claims 201-203, in view of this reference be withdrawn.

Turning now to the Brantigan '327 reference, it was suggested in the Office Action that the annular plugs of the Brantigan implant are inherently capable of distraction and of being inserted one after another. It was hypothesized that contrary to the disclosure in Brantigan the annular plugs could be inserted "sideways", presumably along the line of the grooves in the top and bottom surfaces of these plugs. Modifying Brantigan in this manner would frustrate one express purpose of the ridges and valleys, namely to prevent expulsion of the implant without the need for anchoring screws or penetration of the vertebral endplates. See, col. 2, lines 67- 68, col. 7, lines 23-28. If the plugs were inserted along the length of the ridges and valleys, as suggested, those ridges and valleys would not resist expulsion of the plug through the opening created in the disc annulus to receive the plugs. Even though the proposed modification to the Brantigan plugs

would frustrate one important feature of that device, Applicants have assumed that this modification is acceptable for the purposes of the present response.

Applicants' claimed invention recites elements that are not only configured for consecutive insertion between the tissue surfaces, but are also configured to distract those tissue surfaces as the elements are received between the surfaces. In order to further highlight this distinction, Applicants have amended claim 117 to stress that the configuration of the elements allows them to perform the distraction as each element is consecutively received.

Even if the Brantigan procedure is modified as suggested in the Final Office Action, the annular plugs cannot be considered to be configured for consecutive insertion and for distracting the tissue surfaces as each element is consecutively inserted. The annular plugs in the Brantigan '327 Patent exhibit no characteristics that could allow any plug to be jammed between tissue surfaces or between plugs already in position.

As explained in Applicants' earlier response, although the term "distraction" is not expressly mentioned in the Brantigan '327 Patent, it is indicated that the disc annulus is stretched so that the vertebrae can engage a disc replacement plug. (Col. 2, lines 59-66). Brantigan further states that, "During surgery, the spinal column is stretched to regain any lost disc space ...", and that, "This stretches the remaining disc tissue and ... the plugs ... are inserted into the opened up disc space ... while mounted on a tool ...". (Col. 6, lines 59-65). Figures 13 and 14 of Brantigan also depict the disc space as being distracted enough to permit direct insertion of the plug 11. It can be appreciated that in the absence of any pre-distraction of the space the ridges on the surfaces of the plug would necessarily dig into the vertebral bodies. This action directly contradicts one of the expressed purposes of the plug in Brantigan, namely to mount the plugs without penetration through the hard faces of the vertebrae. Col. 7, lines 23-25.

Thus, it is apparent that Brantigan does not contemplate that the plugs 11 would be capable of distracting tissue surfaces as the plugs are consecutively inserted, as required by Applicants' claim 117. The Final Office Action has apparently construed the recitation of distraction in claim 117 as an end result once all the elements are in place. While it is true that both the Brantigan plugs and Applicants' claimed elements can maintain distraction once the construct is complete, only Applicants' claimed invention is configured to actively distract while each element is inserted. Again, the structure of the Brantigan plugs makes it clear that space for

insertion of the plugs must already be available, otherwise the plug will just butt up against the vertebral bodies or a plug already in position.

In view of the foregoing arguments and amendments, it is believed that all of the pending claims 117, 118, 121, 125-129 and 201-204 are allowable over the art of record. Action toward a Notice of Allowance is earnestly requested.

Respectfully Submitted,

A handwritten signature in black ink, reading "Michael D. Beck". The signature is fluid and cursive, with the first name "Michael" and last name "Beck" clearly legible.

June 13, 2006

Michael D. Beck
Registration No. 32,722
Maginot, Moore & Beck
Bank One Center/Tower
111 Monument Circle, Suite 3250
Indianapolis, Indiana 46204-5115
Telephone: (317) 638-2922
e-mail: mdbeck@maginot.com